

### REMARKS

Applicants' attorney is appreciative of the interview granted by Examiners Krass and Ostrup on October 7, 2003. At that interview, it was proposed by the Examiners that the claims should define the context in which the buffer pH is attained in order to properly define the invention.

In accordance with the suggestions made at the interview, claims 1, 10, 11 and 22 have now been amended that the buffer of the invention is sufficient to buffer gastric acidity to a pH of between 3 and 7. These amendments are supported by the specification in the paragraph bridging pages 1 and 2 ("it makes it possible to reduce the gastric acidity...") and in the paragraph at page 2, lines 13-22 ("which will develop a buffer effect in a liquid, generally water, when they are taken, or in the stomach after they have been taken"). The discussion in the specification makes it clear that the phloroglucinol should be at a pH of between 3 and 7 in order to be most effective, and that it is in the stomach, when the phloroglucinol is exposed to gastric acidity, that this pH should be maintained.

Moreover, *in vivo* data using mice presented on pages 5 and 6 of the specification establishes that the buffered compositions of the invention are more effective as an antispasmodic than the non-buffered oral compositions of the prior art, and generally as effective as the intra-muscular compositions of the prior art.

Claims 1-28 have been rejected under 35 USC 103 over Lafon taken together with Blonde and Bayer Bitterfeld.

The Lafon reference discloses phloroglucinol in combination with Tyrode liquid which is a salt solution and which is alleged to be a buffer. However, as previously noted, Tyrode solution is present only because the

phloroglucinol is being used *in vitro* to study its effect on the duodena of rats which are being maintained alive in Tyrode solution. There is no disclosure or suggestion of using a buffer in conjunction with orally administered phloroglucinol. Indeed, Lafon discloses oral administration in combination with "diluent and carriers" as set forth on page 3 of the reference, but these diluents and carriers are not buffer systems capable of maintaining gastric acidity at a pH of 3 to 7.

The Blonde reference discloses lyophilizates containing phloroglucinol which are used as sweetening compositions. The products are in lump form, similar to lump sugar, which dissolve in water and drinks due to their porous nature. The lumps do not however contain a buffer as defined in the claimed invention.

The Bayer Bitterfeld reference describes Alka Seltzer, an effervescent composition with a pH of between 5 and 7, used for treatment of upset stomach and/or hyperacidity. The Office Action alleges that it would have been obvious to formulate the phloroglucinol compositions of Lafon and Blonde in the form of an "Alka Seltzer" type effervescent composition to achieve rapid dissolution and treat the stomach. Applicants strongly disagree.

With regard to the sweetening type compositions of Blonde, such compositions are not formulated as effervescent compositions; lump sugar is not effervescent and there is no motivation to make the lump sweetener of Blonde effervescent either. Moreover, the buffer used in Alka Seltzer would change the taste of the sweetener of Blonde, and this is additional motivation not to make the cited combination.

As regards the composition of Lafon, the Office Action alleges that since Alka Seltzer is used to treat upset

stomachs, and phloroglucinol is used as an antispasmodic, the uses are sufficiently similar to suggest a combination of phloroglucinol and Alka Seltzer. Applicants disagree; the uses are not similar and an antispasmodic treatment is not the same as or similar to an antacid treatment.

Moreover, even if the combination were alleged to be in some way *prima facie* obvious, Applicants have rebutted such an allegation by showing that phloroglucinol should be buffered to a pH of 3 to 7 in order to enhance the antispasmodic effect. This enhancement of the antispasmodic effect is not disclosed or suggested by the prior art.

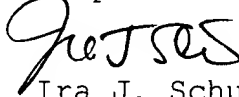
Withdrawal of this rejection is requested.

Claim 22 has been objected to in its use of the word "maintain" and this word has now been deleted.

Claims 22-28 have been rejected under 35 USC 112, 2<sup>nd</sup> paragraph, on the basis that "the medium" in claim 22 lacks antecedent basis. In view of the amendment of claim 22, withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicants submit the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



Ira J. Schultz

Registration No. 28666